United States Court of Appeals
For the Eighth Circuit

No. 19-2899

In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation

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George Amador

Plaintiff - Appellant

v.

3M Company; Arizant Healthcare, Inc.

Defendants - Appellees

Appeal from United States District Court
for the District of Minnesota

Submitted: March 16, 2021
Filed: August 16, 2021

Before GRUENDER, KELLY, and GRASZ, Circuit Judges.

GRUENDER, Circuit Judge.

In December 2015, the Judicial Panel on Multidistrict Litigation created and centralized the *In re Bair Hugger Forced Air Warming Devices Products Liability Litigation* ("MDL") in the District of Minnesota ("MDL court") for coordinated

pretrial proceedings. Plaintiffs[1] in the MDL have brought claims against 3M Company and its now-defunct, wholly owned subsidiary Arizant Healthcare, Inc. (collectively, "3M"). Plaintiffs assert that they contracted periprosthetic joint infections ("PJIs") due to the use of 3M's Bair Hugger, a convective (or "forced-air") patient-warming device, during their orthopedic-implant surgeries. In July 2019, on 3M's motion, the MDL court excluded Plaintiffs' general-causation medical experts as well as one of their engineering experts, and it then granted 3M summary judgment as to all of Plaintiffs' claims. Subsequently, the MDL court entered an MDL-wide final judgment.

Plaintiffs appeal. First, they argue that the MDL court abused its discretion in excluding their general-causation medical experts and engineering expert. Second, they argue that the MDL court erred in granting 3M summary judgment whether or not those experts were properly excluded. Third, they argue that the MDL court abused its discretion in denying Plaintiffs' request for certain discovery. And fourth, they argue that the MDL court abused its discretion in ordering certain filings on its docket to remain sealed. Additionally, on appeal, Plaintiffs ask us to unseal those parts of the appellate record that duplicate the filings whose sealing on the MDL court's docket they challenge.

We reverse in full the exclusion of Plaintiffs' general-causation medical experts and reverse in part the exclusion of their engineering expert. We reverse the grant of summary judgment in favor of 3M. We affirm the discovery order that Plaintiffs challenge. We affirm the MDL court's decision to seal the filings Plaintiffs seek to have unsealed. And we deny Plaintiffs' motion to unseal those same filings on our own docket.

[1]Although George Amador is the captioned Plaintiff-Appellant, this appeal is brought by all Plaintiffs in the MDL to challenge several MDL-wide rulings.

I.

In the mid-1980s, Dr. Scott Augustine invented the Bair Hugger, a forced-air device used to keep patients warm during surgery so as to stave off hypothermia-related complications that can arise during or after surgery. The device consists of a central heating unit, a hose, and a disposable perforated blanket that is placed over the patient. The central unit, which is often situated on or near the floor when in use, draws in air through a filter, warms that air (usually to a temperature significantly above the operating-room temperature), and blows it through the hose into the perforated blanket. The air exits the blanket through the perforations and keeps the patient warm. Typically, both the patient and the blanket are covered with surgical draping during operations, and the blanket is placed on a part of the body away from the surgical site, so the air does not blow directly onto the surgical site.

Dr. Augustine marketed and sold the Bair Hugger through Augustine Medical, Inc., the company he founded and led as CEO until 2004. Around that time, Dr. Augustine was forced to leave Augustine Medical while under investigation for Medicare fraud. Augustine Medical then reorganized, and the division of the company that retained the Bair Hugger product line changed its name to Arizant Healthcare. In 2010, 3M acquired Arizant Healthcare and the Bair Hugger product line. Arizant Healthcare was dissolved in December 2014.

After leaving Augustine Medical, Dr. Augustine developed the HotDog, a patient-warming device that transfers heat conductively to the patient by direct contact with the patient's skin rather than by forced hot air. He then began a campaign to discredit his old invention and promote his new one. These efforts bore fruit. In March 2013, a plaintiff sued 3M and Arizant Healthcare in Texas state court, claiming that he contracted a PJI due to the Bair Hugger's use in his hip-replacement surgery. Dr. Augustine worked with the law firm representing that plaintiff to prepare a "litigation guide" and solicitation letter for the purpose of fomenting more litigation against 3M. By December 2015, more than sixty materially similar cases against 3M had been filed in or removed to federal district

courts around the country. At that time, the Judicial Panel on Multidistrict Litigation ordered these cases centralized in the District of Minnesota for consolidated pretrial proceedings. *See* 28 U.S.C. § 1407(a). Nearly 6,000 lawsuits have since been filed as part of the MDL.

In these cases, Plaintiffs allege that they suffered PJIs from the use of the Bair Hugger during their orthopedic-implant surgeries. PJIs are frequently caused by the introduction of microbes into the surgical site during surgery. Bacterial contamination is a particularly significant threat in orthopedic-implant surgeries because a PJI can be caused by very few microbes, possibly even a single bacterium. For this reason, it is standard for such surgeries to take place in "ultra-clean ventilation" operating rooms, where air is blown into the operating room through high-efficiency particulate air ("HEPA") filtration at a uniform velocity. This HEPA-filtered "laminar" airflow blows over the patient, reducing the likelihood that operating-room airflow will carry ambient bacteria from nonsterile areas of the operating room into the surgical site.

Plaintiffs advance two theories for how the Bair Hugger caused their PJIs during their orthopedic-implant surgeries. According to the "airflow disruption" theory, waste heat from the Bair Hugger creates convection currents that carry ambient bacteria from nonsterile areas of the operating room to the surgical site despite the laminar airflow, resulting in PJIs. According to the "dirty machine" theory, the Bair Hugger is internally contaminated with bacteria, which are blown through the blanket into the operating room, where they become ambient and eventually reach the surgical site, resulting in PJIs.

In the master long-form complaint filed in the MDL, Plaintiffs asserted fourteen state-law claims against 3M, including negligence and strict liability (for failure to warn, defective design, and defective manufacture), among others.

During discovery, Plaintiffs subpoenaed a third party, VitaHEAT Medical, LLC, to produce discovery regarding its "UB3," a conductive patient-warming

device. Plaintiffs alleged that the UB3 was an alternative design to the Bair Hugger, making this discovery ostensibly relevant to their design-defect claims. *See generally* 63A Am. Jur. 2d *Products Liability* § 894 (May 2021 update) ("The existence of an alternative design may be used to establish that a product was unreasonably dangerous due to a design defect, and in some jurisdictions may be required."). VitaHEAT objected on relevancy grounds, arguing that the UB3 was too different from the Bair Hugger to count as an "alternative design" for product-liability purposes. Plaintiffs then filed what they captioned a "motion to overrule" this relevancy objection. The MDL court denied this motion, agreeing that conductive patient-warming devices like the UB3 are too dissimilar from the Bair Hugger to qualify as "alternative designs," meaning that this discovery was not relevant. *Cf. United States v. One Assortment of 93 NFA Regulated Weapons*, 897 F.3d 961, 966 (8th Cir. 2018) ("The Federal Rules of Civil Procedure limit discovery to that which 'is relevant to any party's claim or defense . . . .'" (quoting Fed. R. Civ. P. 26(b)(1))).

The parties jointly agreed to a protective order to limit the disclosure of confidential information that might be contained in filings entered on the MDL docket. Pursuant to this protective order, the parties submitted numerous filings under seal over the course of the litigation. As relevant to this appeal, 3M sought to keep seven such filings under seal over Plaintiffs' objection, asserting that it would suffer competitive harm if any was unsealed. The MDL court agreed and ordered these files kept under seal.

As the litigation progressed, 3M moved to exclude Plaintiffs' general-causation medical experts (Dr. Jonathan M. Samet, an epidemiologist; Dr. William Jarvis, an infectious-disease specialist; and Dr. Michael J. Stonnington, an orthopedic surgeon) as well as Plaintiffs' engineering experts (including Dr. Said Elghobashi and Michael Buck). 3M also filed a motion for summary judgment contingent on the exclusion of Plaintiffs' general-causation medical experts. The MDL court denied in pertinent part the motion to exclude those experts and denied the motion for summary judgment.

Subsequently, *Gareis v. 3M Co.* became the first bellwether trial in the MDL. *See generally* 156 Am. Jur. *Trials* § 219 (May 2021 update) (explaining the bellwether-trial process in mass-tort litigation). Ruling on pretrial motions in *Gareis*, the MDL court excluded evidence of Plaintiffs' dirty-machine theory. The case then proceeded to trial on the airflow-disruption theory, and Plaintiffs' experts Dr. Jarvis, Dr. Stonnington, and Dr. Elghobashi (among others) testified. After an approximately two-week trial, the jury returned a verdict for 3M.

After the *Gareis* trial, 3M moved for reconsideration of the MDL court's orders refusing to exclude Plaintiffs' general-causation medical experts as well as Dr. Elghobashi and denying 3M summary judgment. The MDL court granted 3M's motion, excluding Plaintiffs' general-causation medical experts as well as Dr. Elghobashi and granting 3M summary judgment on all claims. The MDL court then entered an MDL-wide final judgment. *See In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) ("A transferee court has the authority to enter dispositive orders terminating cases consolidated under 28 U.S.C. § 1407.").

Plaintiffs appeal, challenging the MDL court's exclusion of their general-causation medical experts and Dr. Elghobashi, the MDL-wide grant of summary judgment in favor of 3M, the discovery ruling regarding conductive patient-warming devices, and the sealing of seven MDL docket entries. Plaintiffs also ask us on appeal to unseal on our own docket the records that they argue should have been unsealed on the MDL court's docket.

II.

We begin by considering Plaintiffs' challenge to the MDL court's exclusion of their general-causation medical experts (Dr. Samet, Dr. Jarvis, and Dr. Stonnington) and engineering expert (Dr. Elghobashi). Dr. Samet, Dr. Jarvis, and Dr. Stonnington each offered general-causation opinions—that is, opinions that the Bair Hugger "is capable of causing the [PJIs] from which" Plaintiffs allegedly

suffered, *see Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010)[2]—based on both the airflow-disruption theory and the dirty-machine theory. Dr. Elghobashi created a computational-fluid-dynamics ("CFD") model to support the airflow-disruption theory. The MDL court generally treated the medical experts as a collective set (their opinions were essentially the same and were founded on much of the same evidence), and it excluded their opinions as unreliable because (1) it concluded there was "too great an analytical gap between the literature and the experts' general causation opinions"; and (2) "the causal inferences made by the experts have not been generally accepted by the scientific community."[3] The MDL court also excluded Dr. Elghobashi's model and opinion because (1) his conclusion about the Bair Hugger's effects in real-world operating rooms relied on an unproven and untested premise, (2) there was too great an analytical gap between the results of his CFD and his conclusion about the Bair Hugger's effects in real-world operating rooms, and (3) the CFD model was developed for litigation.

For the following reasons, we reverse in full the exclusion of the medical experts' opinions and reverse in part the exclusion of Dr. Elghobashi's model and opinion. We first recite the principles that govern our analysis. We then analyze the reasons given by the MDL court for excluding the experts.

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[2]The opinions in question did not address specific causation—whether the Bair Hugger "in fact caused the harm from which" any particular MDL plaintiff suffered. *See id.*

[3]The MDL court articulated a third reason; namely, that "the experts failed to consider obvious alternative explanations." This reason applies specifically to the medical experts' treatment of the epidemiological study on which they relied, *see infra* Section II.B.1, that found an association between forced-air warming and PJIs, *see* Federal Judicial Center, *Reference Manual on Scientific Evidence* at 597-600 (3d ed. 2011) (explaining that "[c]onsideration of alternative explanations" is one of nine factors that "guide epidemiologists in making judgments about [general] causation" based on a study or studies that find an association). The MDL court discussed this same issue in its analysis of the "analytical gaps" between that study and the experts' opinions. Accordingly, we consider this point in assessing the MDL court's "analytical gaps" analysis.

A.

As the proponent of the expert testimony in question, Plaintiffs have the burden to prove its admissibility by a preponderance of the evidence. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). Federal Rule of Evidence 702 governs the admissibility of expert testimony, and under this rule the district court is "vested with a gatekeeping function, ensuring that 'any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *Union Pac. R.R. v. Progress Rail Servs. Corp.*, 778 F.3d 704, 709 (8th Cir. 2015) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). In exercising this gatekeeping function, the district court has "broad discretion," and "on appeal we will not disturb a decision concerning the exclusion of expert testimony absent an abuse of that discretion." *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006).

That said, we have recognized that the "liberal thrust" of Rule 702 regarding the admissibility of expert testimony creates "an intriguing juxtaposition with our oft-repeated abuse-of-discretion standard of review." *Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 562 (8th Cir. 2014). "While we adhere to this discretionary standard for review of the district court's Rule 702 gatekeeping decision, cases are legion that, correctly, under *Daubert*, call for the liberal admission of expert testimony." *Id.* (collecting authorities).

Rule 702's "screening requirement" has been "boiled down to a three-part test." *Id.* at 561. First, the testimony must be useful to the finder of fact in deciding the ultimate issue of fact, meaning it must be relevant. *See id.* Second, the expert must be qualified to assist the finder of fact. *Id.* Third, the testimony must be reliable or trustworthy in an evidentiary sense. *Id.* At issue here is the third part of this test—whether Plaintiffs' experts' proposed testimony meets Rule 702's reliability requirement. "The standard for judging the evidentiary reliability of expert evidence is 'lower than the merits standard of correctness.'" *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)).

The reliability inquiry is a "flexible" one, with "[m]any factors" bearing on it. *Daubert*, 509 U.S. at 593-94. In *Daubert*, the Court articulated "four non-exclusive factors" relevant to this inquiry. *Johnson*, 754 F.3d at 562. These factors are (1) whether the expert's theory or technique can be or has been tested, (2) whether the theory or technique has been subjected to peer review or publication, (3) the known or potential rate of error of the theory or technique, and (4) whether the technique or theory is generally accepted. *See id.*; *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 297 (8th Cir. 1996). Factors recognized since *Daubert* include "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

Additionally, while *Daubert* instructed that the focus of the reliability inquiry "must be solely on principles and methodology, not on the conclusions that they generate," 509 U.S. at 595, the Supreme Court later clarified that "conclusions and methodology are not entirely distinct from one another," *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Thus, "a district court's focus on principles and methodology need not completely pretermit judicial consideration of an expert's conclusions," *Kuhn*, 686 F.3d at 625 (internal quotation marks omitted), and a district court may exclude expert testimony if it finds "that there is simply too great an analytical gap between the data and the opinion proffered," *Joiner*, 522 U.S. at 146. Or, to put it in the language we have frequently used both before and after *Daubert* and *Joiner*, a district court may exclude an expert's opinion if it is "so fundamentally unsupported" by its factual basis "that it can offer no assistance to the jury." *E.g.*, *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988); *United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir. 2011).

When a district court excludes an expert's opinion for being fundamentally unsupported, yet another "intriguing juxtaposition" is evident in our case law. *See Johnson*, 754 F.3d at 562. On the one hand, we have recognized that we owe "significant deference" to the district court's "determination that expert testimony is

excessively speculative," and we "can reverse only if we are convinced that the District Court made a clear error of judgment on the basis of the record before it." *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003) (internal quotation marks omitted). On the other hand, we have stated numerous times that, "[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *E.g.*, *United States v. Coutentos*, 651 F.3d 809, 820 (8th Cir. 2011); *see also Klingenberg v. Vulcan Ladder USA, LLC*, 936 F.3d 824, 829-30 (8th Cir. 2019) (distinguishing cases where we affirmed the exclusion of experts' opinions as too speculative because, in those cases, the experts' opinions were "wholly speculative," "connected to the facts by only the expert's *ipse dixit*," "patent speculation," "pure conjecture," and "vague theorizing based upon general principles").

Thus, excluding an expert's opinion for being fundamentally unsupported is an exception to the general rule that "[g]aps in an expert witness's . . . knowledge" go to weight, not admissibility. *See Robinson v. GEICO Gen. Ins.*, 447 F.3d 1096, 1100 (8th Cir. 2006); *cf. Finch*, 630 F.3d at 1062 ("Doubts regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility." (brackets omitted)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means" of addressing "shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

With these principles in mind, we analyze the reasons provided by the MDL court for excluding Plaintiffs' general-causation medical experts and Dr. Elghobashi (whose CFD model and testimony formed part of the factual basis for the general-causation medical experts' opinions).

B.

We first consider the MDL court's determination that "too great an analytical gap" existed between "the literature" and Plaintiffs' medical experts' general-

causation opinions. This literature falls generally into two categories: (1) an epidemiological study reporting an association between forced-air warming and PJIs; and (2) studies and reports ostensibly supporting both of Plaintiffs' mechanistic theories of causation. We consider this evidence to assess whether the MDL court "made a clear error of judgment on the basis of the record before it" in finding the experts' opinions too speculative to be admitted. *See Grp. Health Plan*, 344 F.3d at 760 (internal quotation marks omitted).

1.

All three medical experts relied on a 2011 observational epidemiological study as support for their conclusion that the Bair Hugger is capable of causing PJIs. *See* P.D. McGovern et al., *Forced-Air Warming and Ultra-Clean Ventilation Do Not Mix*, 93-B J. Bone & Joint Surgery 1537 (2011) ("McGovern 2011"). As an observational epidemiological study, McGovern 2011 explored whether forced-air warming was associated with an increased rate of PJIs by comparing a group of individuals warmed convectively to a group of individuals warmed conductively. *See id.* at 1537. *See generally Reference Manual*, *supra*, at 552, 555-56.

Specifically, McGovern 2011 reviewed infection data from 1,437 hip- or knee-replacement surgeries performed at a particular hospital for a 2.5-year period. *Id.* at 1537, 1540. From July 2008 to March 2010, the patients were warmed with Bair Huggers; from March 2010 to June 2010, the hospital gradually transitioned to using conductive patient-warming devices; and from June 2010 to the end of the study, the patients were warmed solely with conductive patient-warming devices. *Id.* at 1540, 1543. The investigators found that patients warmed convectively were nearly four times more likely to contract a PJI than patients warmed conductively. *Id.* at 1541. The authors of McGovern 2011 acknowledged that the study did "not establish a causal basis" for this association. *Id.* at 1543. And they acknowledged

that their findings may have been "confounded"[4] by "other infection control measures instituted by the hospital" during the study period (specifically identifying two such potentially confounding measures) and that they were "unable to consider all [patient-medical-history] factors" associated with PJIs, including a number of "important predictors for deep infection," due to limited data in the records they reviewed. *Id.*

The MDL court found that McGovern 2011 itself was sufficiently reliable to be admitted. But the MDL court faulted the experts' reliance on it in ways that contributed to the analytical gap it found. For instance, the MDL court deemed it unreliable for the experts to draw an inference of causation from this study when the study disclaimed having proved causation. The MDL court also faulted how the experts handled the study's limitations.

As for the first point, we disagree that it is *per se* unreliable for an expert to draw an inference of causation from an epidemiological study that disclaimed proving causation. "[E]pidemiology cannot prove causation." *Reference Manual*, *supra*, at 598. Instead, epidemiology enables experts to find associations, which by themselves do not entail causation. *See id.* at 552-53, 598. But an observational study such as McGovern 2011 "can be brought to bear" on the question of causation, *id.* at 217, and "can be very useful" to answering that question, *id.* at 221. Ultimately "causation is a judgment for epidemiologists and others interpreting the epidemiologic data." *Id.* at 598; *see also id.* at 222 ("In the end, deciding whether associations are causal typically . . . rests on scientific judgment."). Thus, it was not necessarily unreliable for the experts to rely on McGovern 2011 to draw an inference of causation just because the study itself recognized, consistent with these principles, that the association did not establish causation. So long as an expert does the work

[4]"Confounding occurs when another causal factor (the confounder) confuses the relationship between the agent of interest and outcome of interest." *Reference Manual*, *supra*, at 591. For instance, if those who drink alcohol are more likely to smoke than those who do not, then smoking may be a confounder in a study finding an association between drinking alcohol and emphysema. *See id.* at 592.

"to bridge the gap between association and causation," a study disclaiming having proven causation may nevertheless support such a conclusion. *See id.* at 218.

We recognize that there is language from *Joiner* that, when taken out of context, might appear to suggest otherwise. *See* 522 U.S. at 145 ("Given that [the authors of the study in question] were unwilling to say that PCB exposure had caused cancer among the workers they examined, their study did not support the experts' conclusion that Joiner's exposure to PCB's caused his cancer."). But the context indicates that the problem with the experts' opinions in that case was that they failed to bridge the gap left by the study in question. *See id.* at 145-46 (recounting numerous issues with the experts' factual basis).

As for the second issue, the MDL court rightly faulted the experts for how they handled McGovern 2011's limitations. "Assessing whether an association is causal requires an understanding of the strengths and weaknesses of the study's design and implementation," and "the key questions" in evaluating epidemiological evidence "are the extent to which a study's limitations compromise its findings and permit inferences about causation." *Reference Manual*, *supra*, at 553. The experts did not adequately address McGovern 2011's limitations. Neither Dr. Jarvis nor Dr. Stonnington mentioned the identified potential confounders or limitations in McGovern 2011 in their reports. Dr. Samet, on the other hand, did address in his report the two potential confounders identified by the authors in the study itself, and he meaningfully explained why in his view these variables did not confound the study's findings. But Dr. Samet did not meaningfully address the other limitations identified by the McGovern 2011 authors except to say that confounding by other factors "seems unlikely" for ostensibly logical reasons.[5]

[5]In the context of discussing this point, the MDL court also faulted Dr. Samet for departing "from his own description of reliable methodology." Specifically, it noted that, with respect to the criterion of consistency that experts use in making judgments about causation, *see Reference Manual*, *supra*, at 600, Dr. Samet noted that that criterion "is generally applied as a consideration related to interpretation of findings of multiple observational studies and hence is not applicable to the single

However, McGovern 2011 was not the only basis on which the experts relied in forming their opinions. In addition to the epidemiological data from McGovern 2011, the experts also relied on studies and reports ostensibly showing plausible mechanisms by which forced-air warming can cause PJIs. *See id.* at 599-600, 604 (identifying the "biological plausibility" of a general-causation theory as one factor guiding epidemiologists in "making judgments about causation" and noting that "[w]hen biological plausibility exists, it lends credence to an inference of causality"). Thus, the experts' failure to handle McGovern 2011's limitations properly is not fatal to the admissibility of their opinions. *See id.* at 599-600 (listing "factors that guide epidemiologists in making judgments about causation"; noting that "there is no threshold number that must exist"; and including among these factors "[b]iological plausibility" along with "[c]onsideration of alternative explanations"). "[A]n inference of causation based on the totality of the evidence" may be reliable even if "no one line of evidence support[s] a reliable inference of causation" by itself. *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 23 (1st Cir. 2011); *see also United States v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007) (noting that whether an expert's opinion testimony satisfies Rule 702 "requires consideration of the *overall* sufficiency of the underlying facts and data"). Accordingly, we turn to the other evidence these experts considered.

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study by McGovern." Because there was only one epidemiological study here, Dr. Samet instead "point[ed] to the consistency of the findings of studies addressing the effect of the Bair Hugger device on particle counts at the surgical site." In context, we do not read this as Dr. Samet misapplying his own methodology but rather acknowledging that the consistency factor was not relevant in its conventional sense but nevertheless the consistency of the mechanistic studies supported an inference of causation from McGovern 2011's finding of an association. As he explained in the next paragraph of his report following the language the MDL court quoted, the mechanistic evidence is consistent with McGovern 2011's findings. The *Reference Manual* directs epidemiologists to consider whether the finding of an association is "consistent with other relevant knowledge," *supra*, at 606, and we fail to see how mechanistic evidence would not count as "other relevant knowledge."

2.

The studies and reports ostensibly showing the "biological plausibility" of the medical experts' general-causation opinions broadly fall into two categories. One set ostensibly supports Plaintiffs' airflow-disruption theory, and the other ostensibly supports Plaintiffs' dirty-machine theory.

a.

All three medical experts relied on Plaintiffs' airflow-disruption theory as a plausible causal mechanism to support their general-causation opinions. Again, according to this theory, waste heat generated by the Bair Hugger creates convection currents that disrupt laminar airflow in operating rooms and transmit nonsterile air to the surgical site, causing PJIs. The experts relied on two general categories of evidence for this theory: (i) Dr. Elghobashi's CFD model and (ii) published studies examining airflow patterns in operating rooms as well as the correlation between particles and bacteria. We consider each category in turn.

i.

To investigate whether forced-air warming "play[s] a role" in transporting squames (skin flakes capable of carrying bacteria that are present in operating rooms) to the surgical site, Dr. Elghobashi prepared a CFD model using large eddy simulation (a way to model fluid turbulence) to simulate the Bair Hugger's effect on airflow and dispersion of squames in an ultra-clean-ventilation operating room. Dr. Samet and Dr. Jarvis relied on Dr. Elghobashi's model. The parties agree, and the MDL court found, that the physics underlying Dr. Elghobashi's model is reliable. Dr. Elghobashi eventually published his model with several coauthors in a peer-reviewed journal. *See* X. He et al., *Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room*, 34 Int'l J. Numerical Methods Biomedical Eng'g, May 2018, at 1 ("He 2018").

Dr. Elghobashi's model replicated an orthopedic operating room, including details such as laminar airflow, an operating table, surgical drapes, a patient underneath the drapes prepared for knee surgery, four surgeons (two with hands extended over the patient, two with hands down), two side tables, two surgical lamps, the Bair Hugger blanket applied to the patient's torso under the drapes, and the Bair Hugger central unit sitting on the floor near the head of the operating table. Dr. Elghobashi accounted for the heat generated by the Bair Hugger as well as heat emanating from other sources, including the surgeons, patient, surgical lamps, and even the exposed surface of the patient's knee. He then included approximately three million 10-µm-sized squames on the floor of the operating room near the operating table (a person sheds on average about ten million squames a day). After inputting a number of airflow-related details, Dr. Elghobashi simulated whether the Bair Hugger could lift these 10-µm-sized squames—particles undisputedly large enough to carry bacteria and thus be "dangerous"—up to four "regions of interest" in the operating room, such as where the surgical tools are kept and the surgical site itself.

Dr. Elghobashi's model showed that, with the Bair Hugger off, the laminar airflow in the operating room was able to disperse the squames away from the regions of interest and to airflow outlets. From this, he concluded that "without the hot air discharged from the blower, the ventilation air circulation alone cannot disperse the squames to the surgical site." But with the Bair Hugger on, within less than a minute the operating-room airflow was sufficiently disrupted by Bair-Hugger-generated heat that convection currents generated by the Bair Hugger lifted a statistically significant number of squames to the regions of interest.

Dr. Elghobashi's conclusion was that "the hot air from the blower and resultant thermal plumes are capable of lifting [squames] and transporting them to the side tables, above the operating table, and the surgical site." And he added that if other variables were introduced into the model, such as movement of medical staff, "then the probability of dispersing the squames to the surgical site will be increased even further." In the published version of the study, Dr. Elghobashi noted that

"several . . . complexities involving other medical equipment in an [operating room], motion of the medical staff, opening and closing of the [operating-room] door, among others are not accounted for," but he asserted that "these complexities may not impact the main conclusions of the present study." He 2018, *supra*, at 18.

The MDL court excluded Dr. Elghobashi's opinion and his model for three reasons. First, it found that his conclusion "relies on an unproven and untested premise." Second, it found that there was "too great an analytical gap between the CFD results and Dr. Elghobashi's conclusion that the surgical team's movement would only increase the Bair Hugger's effect in the real world." Third, Dr. Elghobashi's CFD model was developed for litigation, raising "concerns about its reliability and objectivity." We conclude that entirely excluding Dr. Elghobashi and his model for these reasons was an abuse of discretion. *See, e.g.*, *United Fire & Cas. Co. v. Whirlpool Corp.*, 704 F.3d 1338, 1341-42 (11th Cir. 2013) (per curiam) (reversing in part the district court's "sweeping exclusion" of an expert's testimony (citing, *inter alia*, *Weisgram v. Marley Co.*, 169 F.3d 514, 518 (8th Cir. 1999))).

The MDL court mainly faulted Dr. Elghobashi for opining that if additional real-world conditions (such as personnel movement) that have a significant impact on airflow disruption were introduced into his model, then the Bair Hugger's effect on the dispersion of squames would be exaggerated in a real-world operating room. We affirm this aspect of the MDL court's exclusion. In neither his expert report nor his published study did Dr. Elghobashi provide support for this assertion, and at the *Gareis* trial he explained that he knew this "based on [his] knowledge" and said to "trust [him] about this." "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

But we do not affirm the MDL court's categorical exclusion of Dr. Elghobashi and his model. Dr. Elghobashi set out to determine whether forced-air warming "play[s] a role in transporting squame particles to the surgical site"; his CFD model tested this hypothesis; and he found that forced-air warming does play a role, at least

in certain operating-room conditions with limited airflow disruptions from other sources. So limited, his conclusion was tested and supported by the CFD model, and the problematic analytical gap found by the MDL court is gone.

Granted, the MDL court also decided to exclude Dr. Elghobashi's testimony and model because they were "developed for litigation." *See generally Lauzon*, 270 F.3d at 687. But, with Dr. Elghobashi's testimony properly limited so as to eliminate the other reasons for its exclusion, this factor alone does not warrant exclusion. The scientific reliability of a "hired gun" expert's testimony can "be shown 'by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication.'" *Lauzon*, 270 F.3d at 693 (quoting *Daubert*, 43 F.3d at 1318). That happened here—Dr. Elghobashi's report in this case appears in a peer-reviewed journal. *See* He 2018, *supra*. In these circumstances—where a "hired gun" expert's work has been peer reviewed and published, and the developed-for-litigation concern is the only remaining reason for excluding the testimony—we conclude that lingering questions of reliability and objectivity go to weight rather than admissibility. *See DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000) ("An expert witness's bias goes to the weight, not the admissibility of the testimony, and should be brought out on cross-examination." (internal quotation marks omitted)).

Accordingly, the MDL court abused its discretion insofar as it excluded all of Dr. Elghobashi's testimony. His testimony, properly limited as we have specified here, is admissible. Therefore, his limited testimony and CFD model may be considered as part of the factual basis for Plaintiffs' medical experts' airflow-disruption-theory-based general-causation opinions.[6]

[6]In a footnote, the MDL court noted that if Dr. Elghobashi's testimony were so limited, it "would not assist the trier of fact in resolving the factual dispute" in the cases in this MDL because every such case will require Plaintiffs to prove specific causation. But Dr. Elghobashi's model and limited testimony are relevant and admissible insofar as they provide part of the factual basis for Plaintiffs' medical experts' general-causation opinions. *See Archer Daniels Midland Co. v. Aon Risk*

As for the support that the CFD model and such limited testimony would provide (if admissible) for the medical experts' general-causation opinions to the extent that they are based on the airflow-disruption theory, the MDL court noted that there was "too great an analytical gap between the CFD results and the medical experts' conclusions that the Bair Hugger causes infection." The MDL court explained that this was because the CFD model did not account for many sources of turbulence often present in a real-world operating room, thus leaving questions unanswered about the real-world effects of the Bair-Hugger-created turbulence. We agree that there are gaps between Dr. Elghobashi's model simulating a "pure operating room" and the opinion that the airflow-disruption theory is a plausible mechanism for how the Bair Hugger causes PJIs in real-world operating rooms. But Dr. Elghobashi's CFD model is not the lone support for the airflow-disruption theory, and whether too great an analytical gap exists here requires consideration of the totality of the evidence on this point. *See W.R. Grace*, 504 F.3d at 765.

ii.

In addition to Dr. Elghobashi's model, the medical experts relied on a number of published studies to find the airflow-disruption theory a plausible mechanism of how the Bair Hugger causes PJIs, thereby supporting their general-causation opinions. The MDL court found that the studies themselves were sufficiently reliable to be admitted. But it concluded that there remained "too great an analytical gap between these studies and the experts' conclusion that the Bair Hugger causes infection" by way of this mechanism. First, the MDL court found that the proposition that the Bair Hugger increases particle-laden airflow over the surgical site was inadequately supported because the studies that the experts cited for this proposition did not simulate "real world" operating-room conditions. Second, the MDL court found that, even assuming this first proposition was correct, the proposition that the particles in this airflow carried bacteria was inadequately

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Servs., Inc. of Minn., 356 F.3d 850, 858 (8th Cir. 2004) ("An expert need not have an opinion on an ultimate issue of fact in order for the testimony to be admissible.").

supported because Dr. Jarvis "admitted" at the *Gareis* trial that no study showed that the Bair Hugger has any impact on particles that are large enough to carry bacteria (other than "perhaps" the CFD model).

As for whether the Bair Hugger increases particle-laden airflow over the surgical site, the MDL court was correct that many of these studies, like Dr. Elghobashi's model, did not test the Bair Hugger's effects on airflow disruption and particle counts with all potentially relevant variables included in the analysis. *See, e.g.*, McGovern 2011, *supra*, at 1537-38 (testing the airflow-disruption hypothesis by using a mannequin warmed underneath surgical draping with the Bair Hugger while having a surgeon stand motionless next to the surgical site and an anesthetist stand at the head of the operating-room table); K.B. Dasari, M. Albrecht & M. Harper, *Effect of Forced-Air Warming on the Performance of Operating Theatre Laminar Flow Ventilation*, 67 Anaesthesia 244, 245, 248 (2012) ("Dasari 2012") (finding that forced-air warming created significant levels of excess heat above and around the surgical site under laminar-airflow conditions compared to conductive warming technologies after applying forced-air warming to a mannequin underneath surgical drapes and having two people walk around in the laminar airflow but acknowledging that "in a working operating [room] there are more people and many other ways by which the system might be disrupted"); A.J. Legg, T. Cannon & A.J. Hamer, *Do Forced Air Patient-Warming Devices Disrupt Unidirectional Downward Airflow?*, 94-B J. Bone & Joint Surgery 254, 255 (2012) ("Legg 2012") (testing the airflow-disruption theory by placing a volunteer draped for surgery with the warmer applied under the drapes on an operating table within an enclosure meant to facilitate laminar airflow and having a surgeon stand within the enclosure, but not including any assistants or instrument trays in the enclosure); A.J. Legg & A.J. Hamer, *Forced-Air Patient Warming Blankets Disrupt Unidirectional Airflow*, 95-B Bone & Joint J. 407, 407 (2013) ("Legg 2013") (using similar conditions as in Legg 2012); Kumar G. Belani et al., *Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance*, 117 Anesthesia & Analgesia 406, 406-07, 410 (2013) ("Belani 2013") (testing the airflow-disruption theory by draping a mannequin, applying warming devices underneath the drapes to the mannequin's

torso, and having an anesthetist stand motionless at the head of the mannequin, but cautioning that their findings were "dependent on [the] exact setup" of the experiment, which omitted "instrument trays and a working surgical team").

These limitations notwithstanding, a few of these studies make findings and observations that ameliorate the problematic gap the MDL court found between the simulated operating-room conditions in these studies and real-world operating rooms. For instance, in McGovern 2011, the authors noted how the surgical lighting, drapes, and personnel in their study created "fragile [airflow] conditions" that facilitated the Bair Hugger's ability to disrupt airflow significantly enough to transmit air from nonsterile areas of the operating room to the surgical site. McGovern 2011, *supra*, at 1542. Similarly, in Belani 2013, the authors found that surgical lighting and drapes magnified the Bair Hugger's effects. Belani 2013, *supra*, at 410. In other words, findings in these studies provide empirical support bridging the analytical gap from simulated operating-room conditions to real-world operating-room conditions. This analytical gap, then, was at least partially illusory.

As for whether particles in the increased airflow over the surgical site include bacteria-laden particles, the MDL court made too much of Dr. Jarvis's "admission." As Dr. Jarvis explained at the *Gareis* trial, the key study on which the medical experts relied to correlate particles with bacteria found a statistically significant association between the presence of bacteria and the presence of particles measuring both 5.0-10.0 µm in diameter and ≥10.0 µm in diameter. *See* Gregory W. Stocks et al., *Predicting Bacterial Populations Based on Airborne Particulates: A Study Performed in Nonlaminar Flow Operating Rooms During Joint Arthroplasty Surgery*, 38 Am. J. Infection Control 199, 199-202 (2010) ("Stocks 2010").[7] The Legg 2012 authors found a statistically significant increase in particles measuring 5.0 µm in size over the surgical site when forced-air warming was used. Legg 2012, *supra*, at 255-56. And, as discussed above, Dr. Elghobashi's (admissible) CFD

[7]This study also noted that "[a]irborne bacteria-carrying particles measure 4 µm to 20 µm." *Id.* at 203.

model showed particles measuring 10.0 µm in size reaching "regions of interest" (including the region simulating the surgical site) with the machine on for a short period of time. In other words, the proposition that the increase in particles caused by the Bair Hugger includes bacteria-laden particles finds support in the record.

The question for the MDL court was whether there was sufficient support in the factual basis for the experts' opinions that the Bair Hugger is capable of causing airflow disruption in a real-world operating room that transmits bacteria to the surgical site. The MDL court held that there was not. But, as we have just seen, there is significant support for the proposition that the Bair Hugger independently is capable of disrupting airflow so as to transmit bacteria to the surgical site when other airflow-disruptive variables are controlled for, and there also is empirical support for the proposition that those other variables can facilitate the Bair Hugger's airflow-disruptive effect in a real-world operating room. Thus, notwithstanding the significant deference owed here, we conclude that the MDL court committed a clear error of judgment on the basis of the record before it, *see Grp. Health Plan*, 344 F.3d at 760, in holding that the experts' general-causation opinions premised on the airflow-disruption theory were "so fundamentally unsupported" that they had to be excluded, *see Loudermill*, 863 F.2d at 570. In light of the evidence the experts relied on to find the airflow-disruption theory a plausible mechanism to explain the association found in McGovern 2011, this was an instance in which our "general rule" that deficiencies in an expert's factual basis go to weight and not admissibility should have been followed. *See, e.g.*, *Klingenberg*, 936 F.3d at 830.

b.

All three medical experts also relied on the dirty-machine theory as a plausible causation mechanism to support their general-causation opinions. Again, according to this theory, the Bair Hugger is capable of emitting bacteria harbored within the machine through the blanket and ultimately to the surgical site, causing PJIs. The experts relied on published studies and reports ostensibly supporting this

mechanistic theory.[8] The MDL court found "too great an analytical gap between the experts' conclusions" and these studies, faulting them for ignoring the limitations in these studies, none of which examined whether contaminated air emitted from the device "could reach the surgical site and cause infection."

For the dirty-machine theory to be plausible and for the experts' opinions to be reliably based on this theory, four premises need to be sufficiently supported in the evidence relied on by the experts. *Cf. Hirchak*, 980 F.3d at 609 (noting that, under Rule 702, "the expert opinion itself—not just one of its several premises—must be 'based on sufficient facts'"). First, the Bair Hugger internally must harbor bacteria in either the central unit or the hose. Second, the Bair Hugger must be capable of blowing that internal contamination into the blanket. Third, that internal contamination must be capable of escaping the blanket. And fourth, that internal contamination must be able to reach the surgical site.

The first premise is well supported by the studies that the experts cite, many of which found that Bair Huggers were internally contaminated with bacteria. *See, e.g.*, M.S. Avidan et al., *Convection Warmers—Not Just Hot Air*, 52 Anaesthesia

[8]According to his deposition testimony, Dr. Jarvis also considered the experiment done by Plaintiffs' engineering expert Michael Buck, in which Buck found that the Bair Hugger emitted out of the blanket 5-10 µm sized particles and >10 µm sized particles. Seemingly because neither Dr. Jarvis nor the other two medical experts cited Buck's experiment in their reports, however, 3M argues that none of these experts relied on Buck's work and so this work cannot be considered part of the factual basis for their opinions. *See Hirchak v. W.W. Grainger, Inc.*, 980 F.3d 605, 609 (8th Cir. 2020) (noting that evidence an expert did not consider cannot rescue the expert's opinion from inadmissibility "by filling its analytical gaps"); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000) (rejecting plaintiffs' attempt to bolster their expert's causation opinion with materials corroborating it because the expert "simply did not rely upon those items in formulating his opinion"). We decline to resolve this point because we find that the studies and reports that the experts undisputedly relied on provide enough of a factual basis to render a clear error of judgment the MDL court's finding of "too great" an analytical gap here.

1073, 1074-75 (1997) ("Avidan 1997"); A.T. Bernards et al., *Persistent* Acinetobacter Baumannii*? Look Inside Your Medical Equipment*, 25 Infection Control & Hosp. Epidemiology 1002, 1002, 1004 (2004) ("Bernards 2004"); Mark Albrecht, Robert Gauthier & David Leaper, *Forced-Air Warming: A Source of Airborne Contamination in the Operating Room?*, 1 Orthopedic Reviews 85, 85-87 (2009) ("Albrecht 2009"); Mark Albrecht et al., *Forced-Air Warming Blowers: An Evaluation of Filtration Adequacy and Airborne Contamination Emissions in the Operating Room*, 39 Am. J. Infection Control 321, 322, 324-25 (2011) ("Albrecht 2011").

The second premise also finds support in these studies. *See, e.g.*, Avidan 1997, *supra*, at 1074 (finding that air blown out of Bair Hugger hoses contained microbes); Albrecht 2009, *supra*, at 85, 87 (finding that Bair Hugger hoses were emitting particles in the size range of airborne microbes).

The third and fourth premises find less support but are not unsupported. On the one hand, one of the studies expressly recognized that, for a "direct risk" from the internal contamination to be present, the airflow from the machines would have to reach the surgical site, and it observed that it was "presently unknown whether this happens" because the blanket "may act as a low-efficiency microbial filter" and "surgical drapes may act as a barrier." *See* Mike Reed et al., *Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne-Contamination Emissions*, 81 Am. Ass'n Nurse Anesthetists J. 275, 279 (2013) ("Reed 2013"). On the other hand, a subsequent report described an incident in which a short-circuit inside a Bair Hugger generated smoke that was emitted through the blanket and deposited as soot on the patient's body in the pattern of the holes in the Bair Hugger blanket, undermining the blanket-as-secondary-filter hypothesis and supporting the third premise. *See* T. Moon et al., *Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient*, 4 Open Access J.

Surgery, May 2017, at 1 ("Moon 2017").[9] And the fourth premise finds support in several sources. For one, in a 2004 report on a bacterial-outbreak investigation, the investigators reported that they traced the outbreak strain to the interior of a ventilator and a Bair Hugger, explained that the outbreak subsided once they cleaned the ventilator and replaced the Bair Hugger's filter, and offered their view that "the outbreak strain was transmitted by being carried on contaminated dust from within the machines to the exterior during operation." Bernards 2004, *supra*, at 1003. Additionally, some of the airflow-disruption studies the experts relied on reported that air from where the blanket exhausted waste heat reached the surgical site and that certain draping arrangements would facilitate that. *See, e.g.*, McGovern 2011, *supra*, at 1537, 1539-40; Belani 2013, *supra*, at 407.

Accordingly, we conclude that it was a clear error of judgment for the MDL court to find that the experts' opinions insofar as they were based on the dirty-machine theory were so fundamentally unsupported that they should be excluded. *See Grp. Health Plan*, 344 F.3d at 760; *Loudermill*, 863 F.2d at 570. Certainly, there are weaknesses in the dirty-machine theory. Again, however, redress for such weaknesses lies in cross-examination and contrary evidence rather than exclusion. *See Bonner*, 259 F.3d at 929; *but cf. Polski v. Quigley Corp.*, 538 F.3d 836, 839-41 & n.4 (8th Cir. 2008) (affirming the exclusion of an expert's causation opinion based on an untested mechanistic theory that the expert himself previously had effectively stated was implausible).

* * *

[9]Moon 2017 does not provide unimpeachable support for the third premise, to be sure, because it was unknown whether the particles blown out of the blanket and onto the patient were of the size capable of carrying bacteria. We note, however, that one of 3M's own experts effectively conceded the validity of the third premise, testifying when asked at deposition that "some particles" blown into the blanket will leave it and that some of those particles "[m]ost likely" will carry bacteria.

In sum, we do not dispute the MDL court's determination that there are weaknesses in the factual basis for Plaintiffs' medical experts' general-causation opinions. On the one hand, they have epidemiological evidence reporting an association between Bair Hugger use and PJIs, but on the other hand they failed to grapple adequately with the shortcomings of that evidence. On the one hand, they have identified two plausible mechanisms explaining this association, but on the other hand there are weaknesses in the supports for both mechanisms.

This said, the question the MDL court ultimately had to answer was whether these shortcomings left "too great an analytical gap" between the factual bases for the experts' opinions and the general-causation opinions themselves, *see Joiner*, 522 U.S. at 146; or, in other words, whether the opinions were "so fundamentally unsupported" that they should be excluded rather than admitted and left to be impeached through cross-examination at trial (as evidently happened effectively at the *Gareis* trial), *see Loudermill*, 863 F.2d at 570. While giving due deference to the MDL court's determination, we nevertheless conclude that the MDL court committed a clear error of judgment on the basis of the record before it in finding that the experts' general-causation opinions were so fundamentally unsupported that they had to be excluded.[10]

We emphasize that this conclusion is a narrow one—again, the standard for admissibility is "lower than the merits standard of correctness," *Kuhn*, 686 F.3d at

[10]In arguing to the contrary, 3M relies heavily on our decision in *Glastetter v. Novartis Pharmaceuticals Corp.*, where we affirmed the exclusion of medical experts who "lacked a proper basis" for their general-causation opinions that a certain medication could cause intracerebral hemorrhages. 252 F.3d 986, 988-89 (8th Cir. 2001) (per curiam). We find *Glastetter* distinguishable, most saliently because the experts in that case had no epidemiological evidence on which to rely to link the medication to its purported effect, *see id.* at 992, unlike Plaintiffs' general-causation experts here, *cf. id.* (noting that "epidemiological studies and reports are much desired by litigants in cases involving medical causation"); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) ("[E]pidemiology is the best evidence of general causation in a toxic tort case.").

625—that turns greatly on the fact that the opinions at issue here address general causation (whether the Bair Hugger can cause a PJI) rather than specific causation (whether the Bair Hugger did cause a particular plaintiff's PJI). *See Junk*, 628 F.3d at 450. In several places in its order excluding the medical experts, the MDL court suggested that the weaknesses in the experts' general-causation evidence, particularly in the evidence regarding the mechanisms of causation, would present significant hurdles for the specific-causation showing these Plaintiffs must make to prevail—that is, that they would not have contracted a PJI but for use of the Bair Hugger during their surgeries. Whether this is so is not at issue in this appeal, and we express no view on it here. We hold only that the MDL court abused its discretion in excluding these experts' general-causation opinions on the basis of excessive analytical gaps.

C.

The MDL court's analytical-gap determination constituted the primary justification for its decision to exclude Plaintiffs' general-causation medical experts. But it did briefly find as well that lack of general acceptance of the causal inferences made by the experts also supported excluding their testimony. In *Daubert*, the Court rejected "a rigid 'general acceptance' requirement" that could alone be dispositive, but it did acknowledge that general acceptance (or lack thereof) "can yet have a bearing on the inquiry." 509 U.S. at 588, 594. However, this factor must be applied while bearing in mind "that a rigid general acceptance requirement would be at odds with the liberal thrust of the Federal Rules and their general approach of relaxing traditional barriers to opinion testimony." *Lauzon*, 270 F.3d at 691 (internal quotation marks omitted).

The MDL court considered three data points in its general-acceptance analysis. First, it noted how, in a statement put out by the 2013 International Consensus Meeting on Periprosthetic Joint Infection, there was a strong consensus that, although forced-air warming devices posed a "theoretical risk," no studies had "shown" an increase in surgical-site infections related to the use of these devices,

and although "[f]urther study" was warranted there was no need to stop using forced-air warming devices based on the evidence at that time. Second, it considered a letter issued by the Food and Drug Administration in 2017 reporting the agency's determination that it had been "unable to identify a consistently reported association" between forced-air warming and surgical-site infection and continuing to recommend using such devices "when clinically warranted." Third, it noted that, in a statement put out by the 2018 International Consensus Meeting on Musculoskeletal Infection, there was a strong consensus that there was "no evidence to definitively link" forced-air warming to an increased risk of PJIs.

Notably, however, in that 2018 statement, the authors of the rationale for the bottom-line consensus recognized that "the literature is conflicting," and they called for further study to examine the issue. And Plaintiffs' experts' general-causation inferences are not without support in the medical community. *See, e.g.*, A.M. Wood et al., *Infection Control Hazards Associated with the Use of Forced-Air Warming in Operating Theatres*, 88 J. Hospital Infection 132, 132 (2014) (concluding, after a review of the literature on the issue, that forced-air warming "does contaminate ultra-clean air ventilation," though acknowledging that "current research" had not shown a "definite link" between forced-air warming and surgical-site infections such as PJIs); *cf. Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (recognizing that "medical knowledge is often uncertain" and that "[l]ack of certainty is not, for a qualified expert, the same thing as guesswork"). Even some of the other authorities 3M calls to our attention as showing a lack of general acceptance acknowledge that "concerns exist" about a link between forced-air warming and surgical-site infections, *see* Melissa D. Kellam, Loraine S. Dieckmann & Paul N. Austin, *Forced-Air Warming Devices and the Risk of Surgical Site Infections*, 98 AORN J. 353, 365 (2013), and suggest modifications to forced-air-warming devices to "reduce the risk" they may pose, *see ECRI Update: You're Getting Warm: Uncovering Forced-Air Warming Units*, ECRI Institute (May 1, 2017).

To exclude the experts' opinions here because their conclusions lacked general acceptance would be to take a side on an issue that is "currently the focus of

extensive scientific research and debate." *See Milward*, 639 F.3d at 22; *cf. Bonner*, 259 F.3d at 929 ("[N]either Rule 702 nor *Daubert* requires that an expert opinion resolve an ultimate issue of fact to a scientific absolute in order to be admissible."). Accordingly, in light of our rejection of the MDL court's analytical-gap rationale for exclusion, we conclude that the lack of general acceptance does not independently justify exclusion of Plaintiffs' general-causation medical experts. *Cf. Milward*, 639 F.3d at 22, 26 (criticizing the district court in that case for placing "undue weight on the lack of general acceptance" of an expert's conclusions about causation and ultimately reversing its exclusion of that expert).

III.

The MDL court's grant of summary judgment to 3M was derivative of its order excluding Plaintiffs' general-causation medical experts and Dr. Elghobashi. Because we reverse in relevant part the exclusion of those experts, we reverse the grant of summary judgment. *See, e.g.*, *Kuhn*, 686 F.3d at 633.[11]

IV.

We next consider Plaintiffs' challenge to the MDL court's discovery ruling prohibiting them on relevancy grounds from obtaining discovery concerning conductive patient-warming devices. Plaintiffs argue that this ruling was an abuse of discretion because the discovery is relevant to their design-defect claims. We find no basis to reverse.

"Appellate review of a trial court's determination concerning discovery matters is very narrow." *McGowan v. Gen. Dynamics Corp.*, 794 F.2d 361, 363 (8th Cir. 1986). "[W]e will only reverse upon a showing of a 'gross abuse of discretion

[11]We thus do not reach Plaintiffs' argument in the alternative that summary judgment was erroneously granted even if the general-causation medical experts and Dr. Elghobashi were properly excluded.

resulting in fundamental unfairness in the trial of the case.'" *Ahlberg v. Chrysler Corp.*, 481 F.3d 630, 637-38 (8th Cir. 2007) (quoting *Firefighters' Inst. for Racial Equality ex rel. Anderson v. City of St. Louis*, 220 F.3d 898, 902 (8th Cir. 2000)).

We assume without deciding that, as Plaintiffs argue, the MDL court erroneously concluded that this discovery was irrelevant across the entire MDL because some states would (or might allow a jury to) recognize conductive patient-warming devices as reasonable alternative designs to convective patient-warming devices. Even so, Plaintiffs have not even argued on appeal, let alone shown, that the MDL court's discovery ruling resulted in fundamental unfairness to them in trying their cases. *See Moses.com Secs., Inc. v. Comprehensive Software Sys., Inc.*, 406 F.3d 1052, 1060 (8th Cir. 2005) (declining to reverse a discovery ruling where the party seeking reversal of the discovery rulings at issue did not specify how the rulings "resulted in fundamental unfairness" and the record did not support a finding that the party "suffered prejudice as a result of the rulings"); *Ahlberg*, 481 F.3d at 634 ("[P]oints not meaningfully argued in an opening brief are waived.").

Even if we considered the point, we would not find fundamental unfairness on this record. Plaintiffs apparently had other reasonable-alternative-design evidence available to them, as is demonstrated by their recitation of studies suggesting that filter-related modifications to the Bair Hugger would make it safer. *See, e.g.*, Restatement (Third) of Torts: Prod. Liab. § 2 cmt. f (Am. Law Inst. 1998) (providing an example of a modified existing product as a reasonable alternative design). In addition, Plaintiffs were permitted discovery regarding other convective warming devices for reasonable-alternative-design purposes. *See id.* ("[O]ther products already available on the market may serve the same or very similar function at lower risk and at comparable cost. Such products may serve as reasonable alternatives to the product in question.").

V.

We now turn to Plaintiffs' challenge to the MDL court's decision to seal certain filings on its own docket. We review the district court's decision to seal records for an abuse of discretion. *IDT Corp. v. eBay*, 709 F.3d 1220, 1223 (8th Cir. 2013).

Plaintiffs take issue with the sealing of seven filings: (1) MDL Docket Entry No. 221-19 (also located at MDL Docket Entry Nos. 347, 887, 938, and 1801); (2) MDL Docket Entry No. 221-20 (also located at MDL Docket Entry Nos. 895 and 1806); (3) MDL Docket Entry No. 340 (also located at MDL Docket Entry No. 944); (4) MDL Docket Entry No. 377 (also located at MDL Docket Entry No. 945); (5) MDL Docket Entry No. 901 (also located at MDL Docket Entry No. 1808); (6) MDL Docket Entry No. 937; and (7) Docket Entry No. 1805 (which is another version of the document at MDL Docket Entry No. 937).[12] As the MDL court found, these documents contain sensitive business and strategic planning information. For each, 3M asserted that it would suffer competitive harm if the document was unsealed. The MDL court agreed and ordered these files kept under seal. Plaintiffs argue this was an abuse of discretion. We find no abuse of discretion.

"[T]here is 'a common-law right of access to judicial records.'" *Webster Groves Sch. Dist. v. Pulitzer Pub. Co.*, 898 F.2d 1371, 1376 (8th Cir. 1990) (quoting *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597 (1978)). "This right of access is not absolute," however, "but requires a weighing of competing interests." *Id.* When this common-law right is implicated, "we give deference to the trial court rather than taking the approach of some circuits and recognizing a 'strong

[12]Plaintiffs assert in passing that "[t]he MDL court erroneously sealed dozens of court records," but in both their opening brief and appellate motion they argue specifically only that these seven records should be unsealed. Accordingly, we decline to consider their challenge to the sealing of any other documents besides these seven. *See McKay v. City of St. Louis*, 960 F.3d 1094, 1099 n.2 (8th Cir. 2020).

presumption' favoring access." *Id.* (quoting *United States v. Webbe*, 791 F.2d 103, 106 (8th Cir. 1986)).

Whether sealing is warranted, the common-law right of access notwithstanding, turns on "the relevant facts and circumstances of the particular case." *Warner Commc'ns*, 435 U.S. at 599. The district court "must consider the degree to which sealing a judicial record would interfere with the interests served by the common-law right of access and balance that interference against the salutary interests served by maintaining confidentiality of the information sought to be sealed." *IDT Corp.*, 709 F.3d at 1223. Interests served by the common-law right include bolstering public confidence in the judicial system by allowing citizens to evaluate the reasonableness and fairness of judicial proceedings, allowing the public to keep a watchful eye on the workings of public agencies, and providing a measure of accountability to the public at large (which pays for the courts). *Id.* at 1222. But these interests have "bowed before the power of a court to insure that its records are not used to gratify private spite," to "promote public scandal," to serve "as reservoirs of libelous statements for press consumption," or to serve "as sources of business information that might harm a litigant's competitive standing." *Warner Commc'ns*, 435 U.S. at 598 (internal quotation marks omitted). The "consideration of competing values" that must be done here is "heavily reliant on the observations and insights of the presiding judge." *Webbe*, 791 F.2d at 106.

Here, the MDL court concluded that keeping the contested records under seal was warranted because they contained sensitive, commercially competitive material "to which [3M's] need to maintain confidentiality . . . outweighs the public's right of access." The record shows that Dr. Augustine—who, as we noted above, created a competitor device to the Bair Hugger and has helped foment this litigation against 3M—has attempted to exploit and misrepresent information learned in this MDL to 3M's detriment and to his commercial benefit. In other words, the MDL court's sealing decision was based on "salutary interests," *see IDT Corp.*, 709 F.3d at 1223, before which the common-law right of access "has bowed," *see Warner Commc'ns*, 435 U.S. at 598. *See also United States v. McDougal*, 103 F.3d 651, 658 (8th Cir.

1996) (agreeing that, "as a matter of public policy," courts "should avoid becoming the instrumentalities of commercial or other private pursuits"). Accordingly, we find no abuse of discretion in this decision.

In arguing that we should hold otherwise, Plaintiffs point out a "[m]odern" trend that "'the weight to be given the presumption of access'" is "'governed by the role of the material at issue in the exercise of Article III judicial power and resultant value of such information to those monitoring the federal courts.'" *IDT Corp.*, 709 F.3d at 1224 (quoting *United States v. Amodeo*, 71 F.3d 1044, 1049 (2d Cir. 1995)). In these cases, "the strong weight to be accorded the public right of access" in some instances derives from the central role the documents in question play "in determining litigants' substantive rights" and "from the need for public monitoring of that conduct." *Amodeo*, 71 F.3d at 1049. "Where testimony or documents play only a negligible role in the performance of Article III duties," however, "the weight of the presumption is low." *Id.* at 1050.

Even assuming this is the correct framework to govern the sealing issue here, *but cf. Webster Groves Sch. Dist.*, 898 F.2d at 1376 (noting that we give deference to the district court's sealing decisions "rather than taking the approach of some circuits and recognizing a 'strong presumption' favoring access"), we nonetheless would find no abuse of discretion. The only place where Plaintiffs indicate that the MDL court "discussed and analyzed" these documents is in a footnote in its *Daubert* reconsideration order where it mentioned in passing that it was "unable to determine" from these documents whether they undermined its general-acceptance analysis. As noted above, the general-acceptance factor played a negligible role in the MDL court's *Daubert* decision. And these documents played a negligible role in the MDL court's general-acceptance analysis. Accordingly, any "presumption of access" to these documents is "low," and the "countervailing reason[s]" justifying sealing here trump the right of access. *See Amodeo*, 71 F.3d at 1050.

Plaintiffs also ask us to join several other circuits and hold that there is a First Amendment presumption of public access to summary-judgment materials (which they contend the contested records are). *See, e.g.*, *Rushford v. New Yorker Magazine, Inc.*, 846 F.2d 249, 253 (4th Cir. 1988). We have yet to decide "whether there is a First Amendment right of public access to the court file in civil proceedings." *IDT Corp.*, 709 F.3d at 1224 n.*. We have said, however, that for such a right to be recognized at least two prerequisites must be satisfied: (1) there is a historical tradition of accessibility to the records in question, and (2) there is a significant positive role for public access in the functioning of the judicial process in question. *Id.* Plaintiffs do not even mention, let alone meaningfully argue, the first prerequisite, so we decline to consider this argument. *See McKay*, 960 F.3d at 1099 n.2.

VI.

Plaintiffs also have filed a motion on appeal asking us to unseal the same documents they want us to order the MDL court to unseal. *See Warner Commc'ns*, 435 U.S. at 598 ("Every court has supervisory power over its own records and files . . . ."). The rationale discussed in Section V for affirming the MDL court's sealing decisions regarding the seven documents at issue applies with equal force here, so we deny Plaintiffs' request for us to unseal these documents.[13]

[13]In their opening brief, Plaintiffs also ask us to unseal "all appellate briefs and appendices provisionally filed under seal." Plaintiffs filed unopposed motions to file redacted versions of their briefs that were provisionally filed under seal and to allow the unsealing of most of the contents in the appellate appendices that also were provisionally filed under seal, and we already granted these motions. To the extent they seek further unsealing, their request appears redundant of the request they make in their appellate motion to unseal, which we deny.

VII.

For the foregoing reasons, we affirm in part and reverse in part the exclusion of Dr. Elghobashi's CFD model and opinion, we reverse the exclusion of Plaintiffs' general-causation medical experts' opinions, we reverse the grant of summary judgment to 3M, we affirm the discovery ruling challenged by Plaintiffs on appeal, and we affirm the decision to seal those filings whose sealing Plaintiffs challenge on appeal. Finally, we deny Plaintiffs' motion on appeal to unseal those same filings.
